THE UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH CAROLINA

FLORENCE DIVISION

United States of America, ex rel, John P. Stainback,	)	C/A NO.:
Plaintiff,	)	
vs.	)	**COMPLAINT** (JURY TRIAL DEMANDED)
Forest Laboratories, Inc. And Forest Pharmaceuticals, Inc.,	)	(False Claims Act, 31 U.S.C. § 3729-3733)
Defendants.	)	**DO NOT PLACE IN PRESS BOX** **DO NOT ENTER ON PACER**

COMES NOW, JOHN P. Stainback, Plaintiff in the above-styled action, by and through his counsel of record, Kevin M. Barth, and states that this is an action brought on behalf of the United States of America by JOHN P. Stainback [hereinafter referred to as "Stainback"] against FOREST LABORATORIES, INC. [hereinafter referred to as "FLI"], FOREST PHARMACEUTICALS, INC. [hereinafter referred to as "FPI"], [hereinafter sometimes collectively referred to as "Defendants"] pursuant to the *Qui Tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. §§ 3729-33 ("Federal FCA" or "FCA").

NATURE OF ACTION

1. The Relator brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law or equitable theory of unjust enrichment.

2. The Relator bases his claims against Defendants for causing the submission of false or fraudulent claims to federal health care programs in violation of 31 U.S.C. §3729(a)(1).

3. Within the time frames detailed below, Defendants engaged in a fraudulent scheme to market and promote Bystolic off label to treat erectile dysfunction and congestive heart failure, and renal failure. Defendants did so even though the Food and Drug Administration ("FDA") had not approved the drug as safe and effective for these uses, and in fact, had issued a letter indicating the opposite.

4. In furtherance of its off label marketing scheme, Defendants disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety and efficacy of Bystolic in treating ED and CHF patients.

5. In addition to its illegal off label marketing scheme, Defendants sosught to induce physicians and others to prescribe Bystolic by providing them with various forms of improper forms of remuneration, including cash payments disguised as grants or consulting fees, and other valuable goods and services, all in violation of the federal anti-kickback statute, 42 U.S.C. §3120a-7b(b).

6. As the direct, proximate, and foreseeable result Defendants' fraudulent course of conduct, as wet forth above and herein, they caused thousands of false or fraudulent claims to be submitted to the federal health care programs for Bystolic

prescriptions that were not covered for off label use and/or were ineligible for payment as a result of improper remunerations.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action under the Federal FCA pursuant to 28 U.S.C. § 1331 and 1345, and 31 U.S.C. §§ 3732(a) and 3730.

8. Venue is appropriate as to each Defendant in that one or more of Defendants can be found in, resides in, and/or transacts business in this judicial district. Additionally, acts proscribed by 31 U.S.C. § 3729 have been committed by one or more of the Defendants in this judicial district. Therefore, within the meaning of 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. § 3732(a), venue is proper.

THE PARTIES

9. Plaintiff John P. Stainback is a citizen of the United States of America. He is a resident of the County of Florence, State of South Carolina. He brings this *Qui Tam* action based upon direct and unique information obtained during the period of his employment as a sales representative with Defendant FPI. John P. Stainback is the original source of all information contained herein and in the Complaint and has provided this information and a Memorandum Pursuant to 31 U.S.C. §3730 (e)(4)(b) and 3730 (b)(2) Disclosing Material Evidence Supporting False Claims Act in compliance with the United States government prior to filing of the Complaint.

10. Defendant Forest Laboratories, Inc. is a Delaware corporation with its principal place of business located at 909 Third Avenue, New York, New York 10022, and with its registered agent located at that same address. Defendant Forest Laboratories, Inc. maintains an office in the State of South Carolina and does business in every state within the United States.

11. Defendant Forest Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Forest Laboratories, Inc. and is a Delaware corporation with its principal offices located at 13600 Shoreline Drive, St. Louis, Missouri 63045, and with its registered agent, United States Corporation Company, located at 221 Bolivar Street, Jefferson City, Missouri 65101. Defendant Forest Pharmaceuticals, Inc. is the marketing and sales arm of Defendant Forest Laboratories, Inc.

THE LAW

12. The Medicare Program, Title XVIII of the Social Security Act, (hereinafter "Medicare") is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. The program is overseen by the United States Department of Health and Human Services through the Centers for Medicare and Medicaid Services ("CMS"). Medicare was designed to be a health insurance program and to provide for the payment of hospital services, medical services and durable medical equipment to persons over sixty-five (65) years of age and others that qualify under the terms and conditions of the Medicare Program. Payments

made under the Medicare Program include payment for certain prescription drugs; among those drugs is the drug at issue in this case, Bystolic. Reimbursement for Medicare claims is made by the United States through CMS which contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS.

13. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services through CMS. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994). Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to financially needy individuals that qualify for Medicaid; among those drugs is the drug at issue in this case, Bystolic.

14. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty,

retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. CHAMP'S pays for, among other items and services, prescription drugs for its beneficiaries; among those drugs is the drug at issue in this case, Bystolic.

15. The federal government, through its Departments of Defense and Veterans Affairs, also maintains and operates medical facilities including hospitals, and receives and uses federal funds from prescription drugs for patients treated at such facilities and otherwise; among those drugs is the drug at issue in this case, Bystolic. In addition, under the Public Health Service Act, the Section 340B Drug Pricing Program, and the Veterans Health Care Act of 1992, the federal government directly or indirectly provides funds to certain other federal agencies and to state and local facilities and programs, including to non-profit disproportionate share hospitals ("DSH"). *See generally* 38 U.S.C. § 8126.

16. The Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, prescription drugs for its beneficiaries; among those drugs is the drug at issue in this case, Bystolic. (Together these programs described in paragraphs 6-10 shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs"). 17. The Federal FCA, 31 U.S.C. § 3729(a)(1)(A) makes "knowingly" presenting or causing to be presented to the United States any false or

fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

17. The Federal FCA, 31 U.S.C. § 3729(a)(1)(B) makes "knowingly" making, using, or causing to be used or made a false record or statement material to a false or fraudulent claim paid or approved by the Government a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

18. The Federal FCA, 31 U.S.C. §. 3729(a)(1)(C) makes any person who conspires to commit a violation of the FCA liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $11,000 for claims made on or after September 29, 1999).

19. The Federal FCA, 31 U.S.C. § 3729(a)(1)(G) makes any person who "knowingly" makes, uses or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, liable for three times the amount of the damages the Government sustains and a civil

monetary penalty of between $5,000 and $10,000 per claim ($5,500 and $1,000 for claims made on or after September 29, 1999).

20. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

21. To be properly reimbursable by a Government Health Care Program, a prescription drug must also meet certain other requirements involving whether the drug is prescribed for an "on label" versus an "off-label" use or indication. The Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301, et seq., prohibits the distribution of new pharmaceutical drugs in interstate commerce unless the Food and Drug Administration ("FDA") has determined that the drug is safe and effective for its intended use. 21 U.S.C. § 355 (a) and (d). An approved drug may be prescribed by doctors for uses other than those approved by the FDA, but manufacturers are prohibited from marketing or promoting the drug for such unapproved or "off-label" uses. 21 U.S.C. § 331(d). If the manufacturer intends to promote the drug for a new unapproved use, an application for the proposed new use must be filed with the FDA (or an exemption therefrom must be obtained) and any promotional

materials concerning unapproved uses must meet strict statutory and regulatory requirements. *See* 21 U.S.C. §§ 360aaa, et seq.

22. Whether a drug is FDA-approved for a particular use determines whether a prescription of the drug is reimbursed under many, if not all, Government Health Insurance Programs, including Medicaid and the programs described above. Reimbursement under Medicaid and these other programs is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. §396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." *Id.* §396r-8(k)(3). A medically accepted indication includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in a specified drug compendia. *Id.* §1396r-8(k)(6). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid. There is a single exception: in certain circumstances Medicaid will reimburse the prescription of certain single-source or multi-source innovator drugs for an "off-label" use where the individual State has determined, inter alia, that the drug is essential to the health of beneficiaries. 42 U.S.C. §1396r8(a)(3).

23. The FFDCA provides criminal penalties for the dissemination of written information to health care providers regarding the safety, effectiveness, or benefit of the use of a drug

that is not described in the FDA approved labeling of the drug (i.e. that is "off-label"), if that written information fails to conform to the law's requirements. 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa. A manufacturer may disseminate information on a new use of a drug only if it meets the specific requirements set forth in 21 U.S.C. § 360aaa.

24. The Defendants in this case have violated the Federal FCA and the FFDCA by engaging in the following alleged conduct from at least 1998 to the present, involving the marketing, selling, prescribing, pricing, and billing of Bystolic, which drug Defendants knew were paid for by Federal Health Care Programs, and which drug Defendant Forest expected the other Defendant and numerous unnamed other persons around the United States to prescribe and administer to their patients and thereafter illegally bill or cause to be billed to Federal Health Care Programs. Defendants' schemes, included, but are not limited to, the following actions, all of which violate the Federal FCA:

(a) Conspiring to create unlawful incentives to provide in exchange for patient referral and prescription business;

(b) Paying money and providing gifts to physicians for the purpose of inducing physicians to prescribe medications manufactured and sold by FLI and FPI;

(c) Accepting and receiving money paid from FLI and FPI to physicians in exchange for promoting and prescribing medications manufactured and sold by FLI and FPI;

(d) Conspiring to make and use false records and statements to get false claims paid by the Government;

(e) Conspiring to defraud the Government by getting false

or fraudulent claims allowed or paid by the Government in furtherance of the object of the conspiracy, which was to promote the sales of drugs by FLI and FPI in exchange for cash payments to the physicians involved;

(f) Knowingly making and using a false record or statement to conceal, avoid or decrease obligations to pay or transmit money or property to the Government; and

(g) Illegal off-label marketing of Bystolic.

FACTS AND ALLEGATIONS

25. FLI manufactures a drug known as Bystolic (Nevibolol). FPI sells and markets Bystolic. Bystolic is a prescription beta blocker for use in the treatment of hypertension. The drug was first introduced to the market in the United States in 2008. Bystolic's principal competing drugs are Metoprolol, Carvadilol and other beta blockers used on patients with congestive heart failure and other heart conditions.

26. The Defendants instructed their sales staff, including the Relator to sell Bystolic by indicating that Bystolic was "three drugs wrapped into one" and that the medication was also effective in the treatment of renal failure and erectile dysfunction. The Defendants provided the sales staff, including Relator, with power point presentations indicating how this drug should be marketed, including the "benefits" of using same, which were in direct conflict with the FDA warning letter previously issued to the Defendants.

27. Over the course of Relator's employment, through late 2010, the sales staff members were being pushed to sell Bystolic to

various types of physicians who would be in a position to prescribe significant amounts of this medication, and to sell same using the "off label" claims not supported by appropriate research, and in direct contravention to the FDA's warnings to them.

28. The same marketing pressures and schemes now exist within Defendants to induce physicians to prescribe Bystolic, which would generate substantial revenue for Forest.

29. Beginning in June, 2008, Relator was employed by FPI as a sales representative for the Pee Dee Region from Clarendon County north to Chesterfield County.

30. Relator and the other sales representative trainees were given quarterly budgets to use for entertaining doctors and paying physicians to present speeches, provide preceptorships or conduct studies funded by Defendants.

31. While Relator was employed by Defendants, he became familiar with and knowledgeable of various aspects of the business practices of Defendant Forest. He learned that many of the illegal practices complained of herein were known to, and encouraged by Defendants. However, in reality, Relator learned that Defendants were more focused on obtaining greater market share and revenues from Bystolic than compliance with federal regulations.

32. Defendants keep written records of physician prescription choices and patterns to determine how much Bystolic is being prescribed. If the physician does not prescribe a sufficient amount of Bystolic, that physician is removed from the approved speakers

list, and no longer receives the speaking fees.

33. The Defendants also maintain computer notes indicating the topics discussed with the various physicians and the methods used by the sales staff to induce the physicians to prescribe Bystolic. However, it is the Relator's understanding that these notes are taken off of the Defendants' computer systems after six months.

34. Defendants FLI and FPI had actual and specific knowledge of the ongoing illegal schemes Relator complained of, and said Defendants created opportunities and incentives for its sales representatives to act in this manner. Defendants even awarded bonuses for sales representatives who succeeded in inducing physicians to prescribe FLI's drugs.

35. FLI's latest annual report, released in April 19, 2011 shows sales in the last fiscal quarter alone were $53.1 million. A 37% increase in sales of Bystolic occurred in the period of 2009 to 2010.

SPECIFIC ACTS OF FEDERAL HEALTH CARE PROGRAM FRAUD COMMITTED BY DEFENDANTS

COUNT ONE
VIOLATIONS OF THE FEDERAL FCA:
31 U.S.C. § 3729(a)(1)(A), (B), and (G)

36. Relator restates and realleges the allegations contained in Paragraphs 1-35 above and the allegations of Count Two below, as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

37. The Defendants knowingly presented or caused to be presented false or fraudulent claims to Federal Health Care Programs

and knowingly made, used or caused to be made or used false statements to get said claims paid by Federal Health Care Programs. Bystolic prescriptions would not have been presented but for the illegal incentives made and received by Defendants, and the illegal off-label marketing, promotion and prescribing activities carried out by Defendants. As a result of this illegal scheme, these claims were improper in whole pursuant to 31 U.S.C. § 3729(a)(1)(A)-(B).

COUNT TWO
CONSPIRACY TO DEFRAUD: FEDERAL FCA,
31 U.S.C. § 3729(a)(1)(C)

38. Relator restates and realleges the allegations contained in Paragraphs 1-37 above and the allegations contained in Count Three below as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

39. Defendants knowingly conspired to defraud the United States causing increased sales of FLI's drugs through illegal off-label marketing of Bystolic, in violation of law. Said actions constitute violations of 31 U.S.C. § 3729(a)(1)(C).

40. Defendants knowingly conspired to violate the FCA by acting together to present or cause false or fraudulent claims to be presented and to make or use false statements which damaged the Federal Health Care Programs. Said claims were improper and should not have been made but for the illegal remunerations which caused the prescriptions of Bystolic to be made. Said actions constitute violations of 31 U.S.C. § 3729(A(1)(c).

COUNT THREE
THE FEDERAL ANTI-KICKBACK STATUTE,
42 U.S.C. § 1320a-7b(b)

41. Relator restates and realleges the allegations contained in Paragraphs 1-40 above and the allegations contained in Count Three below as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

42. The federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and could result in the provision of goods and services that are medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form. The statute was enacted in 1972; Congress strengthened it in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603 §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

43. The AKS prohibits any person or entity from offering, making, or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

> (b) Illegal remuneration
>
> * * *
>
> (2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person - -
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service or item for which payment may be made in whole or in part under a federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

44. Under the AKS, drug companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to prescribe drugs for which payment may be made by federal health care programs.

45. The AKS not only prohibits outright bribes, but also prohibits any remuneration by a drug company to a physician that has as one of its purposes inducement of the physician to write prescriptions for the company's pharmaceutical products.

COUNT FOUR
UNJUST ENRICHMENT

46. Relator restates and realleges the allegations contained in Paragraphs 1-45 above and the allegations contained in Count Three below as if each were stated herein in their entirety and said allegations are incorporated herein by reference.

47. The United States claims the recovery of all monies by which Defendants have been unjustly enriched.

48. As a consequence of the acts set forth above, Defendants were unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYERS FOR RELIEF

WHEREFORE, Relator John P. Stainback, demands and prays that judgment be entered as follows against each Defendant under the Federal FCA claims as follows:

(a) In favor of the Relator against each Defendant, jointly and severally, for treble the amount of damages to Federal Health Care Programs from the marketing, selling, prescribing, pricing and billing of Bystolic, plus maximum civil penalties of Eleven Thousand Dollars ($11,000.00) for each false claim;

(b) In favor of the Relator against each Defendant, jointly and severally, for disgorgement of the profits earned by Defendants as a result of their illegal scheme;

(c)In favor of the Relator for the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) to include reasonable expenses, attorney fees and costs incurred by Relator;

(d) In favor of Relator against Defendants for all available damages and relief under 31 U.S.C. § 3730(h), including, without limitation, two times back pay plus interest (and prejudgment interest), reinstatement, front pay, and compensation for any special damages and/or exemplary or punitive damages, and litigation costs, and attorneys' fees.

(e) On the fourth count for unjust enrichment, for the damages sustained and/or amounts by which Defendants were unjustly enriched or by which Defendants retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

(f) For all costs of the Federal FCA civil action;

(g) In favor of the Relator for such other and further relief as this Court deems to be just and equitable.

JURY DEMAND

RELATOR DEMANDS A TRIAL BY JURY BE HAD AS TO THE ALLEGATIONS AGAINST EACH DEFENDANT SET FORTH HEREIN.

s/Kevin M. Barth
KEVIN M. BARTH
FED. CT. ID# 1584
POST OFFICE BOX 107
FLORENCE, SOUTH CAROLINA 29503
(843) 662-6301
E-mail: kbarth@hbbh.net
ATTORNEY FOR RELATOR

Florence, South Carolina
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